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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,493	10/29/2001	Eric Andre DesRosiers	701826-052040	7468

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EXAMINER

MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/055,493

Applicant(s)

DESROSIERS, ERIC ANDRE

Examiner

Abdel A. Mohamed

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

#### **ACKNOWLEDGMENT OF PRELIMINARY AMENDMENT, IDS AND STATUS OF THE CLAIMS**

1. The preliminary amendment filed 10/29/01 and the information disclosure statement (IDS) and Form PTO-1449 filed 7/15/02 are acknowledged, entered and considered. Claims 1-36 are present for examination.

#### **CLAIMS REJECTION-35 U.S.C. § 112<sup>2nd</sup> PARAGRAPH**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation "substantially similar" because it is unclear as to how much the biocompatible solution is substantially similar to a fatty acid mixture normally present in a healthy fat pad. Appropriate clarification is required.

Claim 1 is inconsistent in the recitation "fat pads" and "fat pad" because the body of the claim recites "fat pad" while the preamble of the claim recites "fat pads". Further, there is no proper antecedent basis "the fat pad" in line 3 because the preamble recites "fat pads". It is believed to be typographical error. Appropriate correction is suggested.

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Claim 1 is indefinite in the recitation "biocompatiable" because the term "biocompatiable" is misspelled. Amendment of the claim to recite "biocompatible" is suggested.

Claim 1 appears to be confusing in the recitation "mPa. s" because it is not clear whether or not the "." is appropriate. Further, Figure 2 shows the unit of "kPa". Thus, it is not clear if Applicant intends to claim the unit recited in Figure 2. Appropriate clarification is required.

Claim 1 is indefinite in the recitation "substantially similar" because it is not clear as to what is substantially similar to a fatty acid mixture. There is no definition of "substantially similar" in the specification. Also, there is no disclosure of fatty acid mixture normally present in a healthy fat pad in the instant disclosure. Only fatty acid composition of heel fat pad is disclosed in Table 1 of the specification. Appropriate clarification is required.

Claims 3 and 16 are indefinite in the recitation "and/or" because it is not clear whether "and" or is it "or" is claim meant in the conjunctive or is the "/" meant to be used in the alternative. Appropriate clarification is required.

Regarding claims 4, 5 and 13, the phrase "and the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "and the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Regarding claims 4 and 5, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 4 and 5 are indefinite in the recitation "their" (line 4) because to what saturated (claim 4) or unsaturated (claim 5) fatty acids does this refer to? All or some and if some, which one? Appropriate clarification is required.

Claims 4, 5, and 9 are indefinite in the recitation "any mixture thereof" and claim 13 in the recitation "a mixture thereof" because it is unclear as to what are the mixtures? Amounts of the components in the mixtures? and which components? Further, with respect to claims 4, 5 and 9 the use of "any" is not appropriate for a Markush species. Appropriate correction is suggested.

Claims 7 and 17 are indefinite in the recitation "to reduce viscosity and to allow..." because it is not clear how much viscosity is reduced and in comparison to what?. Appropriate clarification is required.

The syntax of claim 8 is indefinite in the recitation "...consisting of water, alcoholic solvents, alkylene glycols and poly-alcohols". Amendment of the claim to recite "...consisting of water, alcoholic solvent, alkylene glycol and poly-alcohol" is suggested.

Claim 11 is indefinite in the recitation "highly-viscous" because it is not clear at what temperature or condition the solution becomes i.e., highly-viscous is not defined in the specification. Appropriate clarification is required.

Claim 12 is indefinite in the recitation "polymer or biopolymer" because "polymer" is a genus and "biopolymer" is a species. The claim either comprises "polymer" or "biopolymer" and not both in the same claim. Appropriate correction is suggested.

Claim 13 is indefinite and confusing in the recitation "substituted derivative thereof" because it is not clear what is the substituted derivative? Appropriate clarification is required.

Claims 14 and 24-26 are indefinite and confusing in the recitation "derivative thereof" because it is not clear what is the derivative? Appropriate clarification is required.

Claim 15 is indefinite in the recitation "a derivative of collagen" because it is not clear what the derivative of collagen is since it is not disclosed in the specification. Appropriate clarification is required.

Claim 15 recite "from the group consisting.....chitosan-based solution, .....chitosan....." It is not clear what is the difference between "chitosan-based solution" and "chitosan" in a Markush format claim. Appropriate clarification is required.

Claim 16 is indefinite in the recitation "a mixture of two or more" because it is not clear how many more than two is more included or excluded 1 or 2 or  $10^3$ . Appropriate clarification is required.

Claim 18 is indefinite in the recitation "natural" because it is not clear what the term "natural" refers since it is not defined in the specification. Appropriate clarification is required.

Claim 18 is indefinite in the recitation "artificial or synthetic" because it is not clear as to their differences. Appropriate correction is suggested.

Claims 21 and 22 are indefinite in the recitation "a self-gelling polymeric solution" and "a thermo-gelling solution", respectively because it is not clear if the gelling occurs at higher or lower temperature. Appropriate clarification is required.

Claim 26 is indefinite in the recitation "elements" because to a chemist "elements" mean element H, O, N, etc. Amendment of the claim to recite "components" is suggested.

Claims 27 and 31 are indefinite in the recitation "said solution comprises a solid component" and "said solution stored under solid form", respectively because solution by definition cannot have solids (See e.g., Chemical Dictionary). Appropriate correction is suggested.

#### **DUPLICATE CLAIMS, WARNING**

3. Applicant is advised that should claim 29 be found allowable, claim 30 will be objected to under 37 CFR 1.75 as being a word for word duplicate. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

**CLAIMS REJECTION-35 U.S.C. § 102(b)**

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Buschmann et al., (Foot & Ankle, Vol. 14, pp. 389-394, 1993)

Claim 36 is directed to a pharmaceutical composition comprising a fatty acid mixture normally present in a healthy fat pad. Similarly, the reference of Buschmann et al., discloses the comparison of the fatty acid compositions of normal heel fat pads and the fatty acid compositions of heel pads in patients (see abstract) as directed to claim 36. To the extent that fatty acid compositions is in a physiological buffer it is considered to be a pharmaceutical composition. Thus, the prior art discloses the invention substantially as claimed, and as such, anticipates claim 36 as drafted.

**CITATION OF RELEVANT PRIOR ART**

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Buschmann et al., (Foot & Ankle, Vol. 14, pp. 389-394, 1993) disclose the comparison of the fatty acid compositions of normal heel fat pads and the fatty acid compositions of heel pads in patients with diabetic peripheral neuropathies of the lower



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extremities, rheumatoid arthritis, peripheral vascular disease, and hereditary sensory neuropathy, which resulted with debilitating degeneration and atrophy of the heel fat pads.

D'Ambrosia, R.D. (Orthopedics, Vol. 10, pp. 137-142, 1987) teaches the injection of steroid for short periods along physical therapy to treat damaged or degenerated fat pads in a patient.

Van Schie et al., (Diabetes Care, Vol. 23, pp. 634-638, 2000) investigate the effectiveness of injecting liquid silicone in the diabetic foot to reduce risk factor for ulceration in a randomized double-blind placebo-controlled trial, wherein the injection with liquid silicone increased localized plantar thickness, reduced plantar pressure, and reduced callus formation.

#### **ALLOWABLE SUBJECT MATTER**

6. Claims 1-35 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action.

#### **REASONS FOR INDICATION OF ALLOWABLE**

##### **SUBJECT MATTERS**

7. The prior art of record not relied upon is considered pertinent to Applicant's disclosure: Although, the treatment of damaged or degenerated fat pads by injecting liquid silicone or steroid as well as the fatty acid compositions of the heel fat pads is conventional and well known in the art; however, none of the cited prior art either

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singularly or in combination disclose, teach or suggest of injecting a solution, which is physico-chemically and mechanically similar to the fatty acid mixtures normally present in a healthy fat pads for treating damaged or degenerated fat pads in a foot of a patient in the manner claimed in the instant invention of claims 1-36.

### CONCLUSION AND FUTURE CORRESPONDENCE

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed number is (571) 272-0955. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The appropriate fax phone number for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196

 Mohamed/AAM

  
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March 8, 2004